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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,730	03/03/2004	Makoto Ozeki	1422-0625P	2621
2292 7590 08/04/2010 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747				
EXAMINER CLAYTOR, DEIRDRE RENEE				
ART UNIT		PAPER NUMBER		
1627				
NOTIFICATION DATE		DELIVERY MODE		
08/04/2010		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

### Office Action Summary

**Application No.**

10/790,730

**Applicant(s)**

OZEKI ET AL.

**Examiner**

Renee Claytor

**Art Unit**

1627

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 March 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 5, 7 and 13 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 5, 7, 13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/22)
- Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Request for Continued Examination***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/11/2010 has been entered.

### ***Response to Arguments***

Applicants argue that the theanine of the present invention exhibits unexpectedly significant amelioration in the symptoms of normofolatemc patients and this effect is unexpected and unpredictable in view of Ueda et al.

It is noted that Ueda et al. does not teach that the patient is having a lack of folate; therefore, absent a teaching that there is a deficiency in folate one would assume that the patient is a normofolatemc patient. Further, Applicants have made a statement that the invention exhibits unexpectedly significant amelioration in the symptoms of normofolatemc patients and this is an unexpected and unpredictable result; however, there is no showing of the criticality of the asserted unexpected result.

Please see the modified rejections below.

***Claim Rejections – 35 U.S.C. § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5, 7 and 13 rejected under 35 U.S.C. 103(a) as being unpatentable over Ueda et al. (U.S. Patent 6,831,103) in view of Hamilton (J Neurol Neurosurg Psychiat, 1960, 23, 56).

Ueda et al. teaches the administration of a theanine-containing composition that is capable of ameliorating symptoms such as anxiogenic symptoms that include those symptoms due to an unidentified cause and associated with diminished homeostasis (Col. 1, lines 13-22; Col. 4, lines 41-61 and Test Example 3). Further, diminished homeostasis is a disorder that falls under the broad term of mood disorder as claimed and is treated with theanine and further symptoms of diminished homeostasis include spiritlessness, aggressiveness, faintheartedness, maudliness and psychological lift. Further, Ueda et al. teaches that diminished homeostasis is a state wherein stably maintaining morphological and physiological conditions in normal ranges in altered and this includes changes in nervous system regulation (Col. 3, lines 60 – Col. 4, lines 1-6). Ueda et al. further teach that theanine may be contained in different types of food or beverages (Col. 6, lines 8-67 – Col. 7, lines 1-17). Ueda et al. is silent as to whether the patient is normofolatemetic or not. However, absence a showing of criticality that the product shows unexpected results in normofolatemetic patients, the invention is deemed

obvious over Ueda et al. Ueda et al. does not specify that the symptoms of mood disorder as feelings of guilt, suicide and retardation:psychomotor; however, Ueda et al. generally teaches treating symptoms of mood disorder which would include all of these symptoms. Primarily anxiogenic symptoms are often indicated in feelings of guilt and suicide. Further diminished homeostasis symptoms read on the symptoms of retardation:psychomotor. Accordingly, Ueda et al. teaches treating mood symptoms which render the present invention obvious.

Ueda et al. do not specifically teach that the mood is assessed by the Hamilton scale or all of the different types of mood listed in claims 9-11.

Hamilton teaches a rating scale for measuring symptoms of mental disorder, including the symptoms such as feelings of guilt, suicide, retardation:psychomotor and diminished insight (see whole document).

Accordingly, it would be obvious to a person of ordinary skill in the art at the time of the invention that the Hamilton scale would be an effective assessment of symptoms of mood disorders because of the teachings of Ueda et al. that theanine containing compositions are effective in treating various types of mood, particularly those associated with anxiety and diminished homeostasis. One would be motivated to use the Hamilton scale because it is a scale commonly used to assess various mood disorders, including depressed states. Therefore, the other factors in the scale would also be measured.

### ***Conclusion***

No claims are allowed.

***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Renee Claytor whose telephone number is (571)272-8394. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Renee Claytor

/SREENI PADMANABHAN/

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Supervisory Patent Examiner, Art Unit 1627